REMARKS

Claims 8-20, 22-28, 30-32, and 44-49 are pending in the application and are presented for reconsideration.

The specification provides support for new claims 44-46. Specifically, the specification recites the insertion of cPPT and CTS sequences into a previously described HIV vector in Naldini *et al.*, Science, vol. 272, pp. 263-267 (1996). *See* specification p. 13, lines 1-3. Naldini *et al.* describes a nucleic acid with sequences required for reverse transcription and packaging ("ψ signals", *see* p. 263, first column), as well as promoter sequences, such as, but not limited to, CMV, which direct the expression of a heterologous gene, by stating:

> The third plasmid, the transducing vector (pHR'), contains cis-acting sequences of HIV required for packaging, reverse transcription, and integration, as well as unique restriction sites for the cloning of hteroloogus complementary DNAs (cDNAs). . . . The *Escherichia coli* β-galactosidase (β-gal) or the firefly luciferase coding sequences were inserted into pHR' downstream of the hCMV immediate early promoter to serve as reporter genes.

Naldini *et al.*, p. 263, third column. Furthermore, in footnote 16, Naldini *et al.* explains:

> Plasmid pHR' was construct by cloning a fragment of the env gene encompassing the RRE and a splice acceptor site between the two LTRs of the HIV-1 proviral DNA. The gag gene was truncated and its reading frame blocked by a frameshift mutation.

Id. at p. 266, FN 16. Finally, new claims 44-46 do not add new matter, because Naldini et al. is incorporated by reference into the specification.

Applicants note that Naldini *et al.*, as well as other references, were cited in Information Disclosure Statements previously submitted, but that they were not acknowledged by the Office. Applicants respectfully request that these references be

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acknowledged by initialing the Form 1449s that were submitted on January 10, 2001, and March 22, 2002.

In addition, new claim 47 was derived from original claim 13. The terms "*Cla*I insert" and "*Eco*RI/*Bam*HI insert" were derived from the information on page 31, lines 9-11 and page 32, lines 15-18, and therefore new claim 47 does not add new matter.

Claims 41 and 43 were rejected under 35 U.S.C. § 102(b) by the Office. *See* Office Action, Paper No. 14, pages 2-4. In addition, claims 41-43 were rejected under 35 U.S.C. § 103. See Office Action, Paper No. 14, pages 4-6. Applicants have cancelled claims 41-43 and respectfully request that the rejections be withdrawn.

Further, claims 1 and 8-32 were rejected under 35 U.S.C. § 112, first paragraph, *see* Office Action, Paper No. 14, page 7, and also under 35 U.S.C. § 112, second paragraph, *see* Office Action, Paper No. 14, pages 8-10. The Office asserted that the reference to Figure 5A renders the claims indefinite and is not supported under the written description requirement. Applicants have cancelled claims 1, 21, and 29, which recited Figure 5A, therefore obviating the rejection. Furthermore, a description of the preparation of a nucleic acid claimed in new claims 44-46 can be found in Example 1 of the specification and in Naldini *et al.,* note 16. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first and second paragraphs, be withdrawn.

In view of the foregoing remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: January 16, 2003

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Appendix to th Amendment of January 16, 2003

IN THE CLAIMS:

Please amend the claims as follows:

11. (AMENDED) A vector comprising the nucleic acid [of claim 1] as claimed in claim 44.

15. (AMENDED) A virus comprising the nucleic acid [of claim 1] as claimed in claim 44.

18. (AMENDED) A recombinant cell comprising the nucleic acid [of claim 1] as claimed in claim 44.

22. (AMENDED) The process [of claim 21] as claimed in claim 45, wherein the efficiency of insertion of the nucleic acid of interest into the target cell nucleus is 30% or greater.

23. (AMENDED) The process [of claim 21] as claimed in claim 45, wherein the nucleic acid of interest is [present on] in a vector.

27. (AMENDED) The process [of claim 21] as claimed in claim 45, wherein the target cell is a non-dividing cell.

28. (AMENDED) The process [of claim 21] as claimed in claim 45, wherein the target cell is a HeLa cell or a hematopoietic cell.

30. (AMENDED) The process [of claim 29] as claimed in claim 46, wherein the nucleic acid is [present on] in a vector.

31. (AMENDED) The process [of claim 29] as claimed in claim 46, wherein the gene of interest is expressed in tissue culture.

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32. (AMENDED) The process [of claim 29] as claimed in claim 46, which further comprises purifying or isolating the product of expression of the gene of interest.

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